

Real world efficacy and safety of nintedanib in idiopathic pulmonary fibrosis: A single center, observational study from India

Deepak Talwar¹, Deepak Kumar Prajapat¹, Dhruv Talwar²

¹Department of Internal Medicine, Metro Centre for Respiratory Diseases, Noida, Uttar Pradesh, India, ²Department of Pulmonary, Critical Care, Allergy and Sleep Medicine, JNMC, Savangi, Maharashtra, India

ABSTRACT

Background: Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis (IPF) has been established by multiple clinical trials. This study aims to assess the efficacy and safety of nintedanib in real-world IPF patients in India. **Methods:** Clinical records of IPF patients (prescribed with nintedanib) visiting tertiary pulmonary care center, between June 2016 and December 2019, were analyzed retrospectively. Data were analyzed for forced vital capacity (FVC), Diffusing capacity of lung for carbon monoxide (DLCO), 6-min walk distance (6-MWD). Acute exacerbations and adverse events were also analyzed. **Results:** A total of 76 IPF patients were prescribed with nintedanib. Drug was prescribed at 100 and 150 mg BD dose to 37 and 39 patients. Ten patients (13.1%), of which eight were over the age of 60 years, died during the study period. Only 42 patients visited for follow-up. Mean baseline FVC was 1.67 L and mean annualized absolute change in FVC and FVC % predicted was -0.07 L and -1.80%, respectively. Mean baseline DLCO was 37.21% and mean annualized absolute change in DLCO % predicted was -2.20%. At follow-up, 1 (2.38%), 17 (40.47%), and 24 (57.14%) patients were at Department of Internal Medicine stage I, II, and III, respectively. Acute exacerbations and adverse events were reported by 48 and 6 patients, respectively. **Conclusion:** Our results support the findings from previous studies, that nintedanib leads to annual decline in parameters such as FVC and DLCO and increased 6-MWD. It was found to be well tolerated in the Indian patients with IPF.

KEY WORDS: Adverse event, diffusing capacity for carbon monoxide, forced vital capacity, idiopathic pulmonary fibrosis, nintedanib

Address for correspondence: Dr. Deepak Talwar, Department of Pulmonary, Critical Care, Allergy and Sleep Medicine, Metro Centre for Respiratory Disease, 94, Noida Road, D Block, Sector 11, Noida - 201 301, Uttar Pradesh, India.
E-mail: dtlung@gmail.com

Submitted: 18-Feb-2021 **Revised:** 05-Jul-2021 **Accepted:** 06-Jul-2021 **Published:** 28-Dec-2021

INTRODUCTION

Idiopathic pulmonary fibrosis (IPF) with the prevalence varying from 2 to 9 per 100,000 population, is a chronic, progressive interstitial lung disease (ILD) of unknown etiology and is associated with rapid decline in lung

function. The disease occurs predominantly in the elderly and occurs more commonly in people exposed to certain risk factors. IPF has a poor prognosis with a median survival time of around 2–3 years.^[1,2] Progression

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How to cite this article: Talwar D, Prajapat DK, Talwar D. Real world efficacy and safety of nintedanib in idiopathic pulmonary fibrosis: A single center, observational study from India. Lung India 2022;39:27-33.

Access this article online	
Quick Response Code: 	Website: www.lungindia.com
	DOI: 10.4103/lungindia.lungindia_393_21

of IPF is monitored using forced vital capacity (FVC) % predicted, diffusing capacity of the lung for carbon monoxide (DLCO), and 6-min walk distance (6-MWD), and clinical and radiological changes. “GAP index” which helps in predicting the prognosis of IPF patients consists of four variables, namely, gender, age, and two physiological parameters (FVC and DLCO).^[3]

The aim of therapy in IPF is to alleviate symptoms and slower the disease progression. While no drug “cures” IPF, antacids help in relieving reflux symptoms and antifibrotics (pirfenidone and nintedanib) decelerate the disease progression.^[3] Nintedanib is a potent small-molecule tyrosine kinase inhibitor of vascular endothelial growth factor receptor, fibroblast growth factor receptor, and platelet-derived growth factor receptor.^[4] The efficacy and safety of nintedanib in IPF were assessed in one phase II trial (TOMORROW, $n = 432$) and two identical phase III (INPULSIS-1 and INPULSIS-2) trials. The trials demonstrated that nintedanib slowed disease progression by significantly reducing the annual rate of decline in FVC. It may also reduce the incidence of acute exacerbations and improve health-related quality of life. Diarrhea was the most common adverse effect of nintedanib, however, most episodes were mild to moderate, and were manageable by dose reduction and treatment interruption.^[5] While the subgroup analyses of INPULSIS showed that nintedanib is effective in broad spectrum of IPF patients typically, in clinical practice, the published literature on its real-world use is limited.^[6] Recently, an Indian study describing the effect of nintedanib in IPF patients in clinical practice was conducted, however, the sample size was very small ($n = 20$).^[7] Therefore, the present study was conceptualized in larger sets of IPF patients to assess the efficacy and safety of nintedanib in real-world settings in India.

METHODS

This was a real-world retrospective study conducted at single center in India.

Study population

Data from clinical records of IPF visiting the tertiary pulmonary care center in North India between June 2016 and December 2019, were analyzed retrospectively. Data were digitized in a specially designed case record form, after removing patient-identifier information. All complete patient records were used for the analysis. Patients diagnosed with IPF based on the European Respiratory Society/American Thoracic Society guidelines, and prescribed nintedanib, were included in the analysis. Patients without any follow-up visits were excluded.

Since patients were followed up in ILD Clinic at the center, recruitment and follow-up was done as per existing protocol where diagnosis is established after multidisciplinary discussion and all patients are followed

up every 8–12 weeks with routine and lung functions evaluation. The ethical approval was taken from the Institutional Ethics Committee for the patient data analysis.

Outcomes assessed

Primary outcomes

Baseline and follow-up data were available, and analyzed for FVC, diffusing capacity for carbon monoxide (DLCO), 6-MWD. The changes in these parameters over 1-year period according to age and last dosage regimen were assessed.

Secondary outcomes

Number of episodes of acute exacerbations, and adverse events (reported by patients or based on lab investigations) were analyzed.

Data analysis

To ensure a more reliable interpretation of changes in various parameters, we included, in respective analyses, only those patients for whom there was a gap of at least 6 months between the first and the last observations. In these subsets of patients, data were annualized based on first and last available values.

Data analysis was done using Python 3.7.3, R studio 1.2.1335 and Microsoft Excel (version 16.31). Descriptive statistics were presented in the form of categorical and continuous variables. Categorical variables (like age, gender) were expressed as percentages. Continuous variables (like FVC, DLCO, 6-MWD) were expressed as means, and the annualized rate was calculated on the linear assumption by using: $Y = m \times x + c$, where m is the slope of the line and calculated as $(\text{value2} - \text{value1}) / (\text{date2} - \text{date1})$, c is the intercept of line and calculated as $(\text{date2} \times \text{value1} - \text{date1} \times \text{value2}) / (\text{date2} - \text{date1})$, y is the value of the variable (FVC, DLCO, 6-MWD) and x is the date.

RESULTS

A total of 76 IPF patients' data were available for the analysis. The mean age of the patient population was 63.1 years, and 57.9% were males. Detailed baseline demographic and clinical characteristics are presented in Table 1. The total duration of nintedanib treatment was 23.2 months. Ten patients (13.1%), of which eight were over the age of 60 years, died during the study period, due to progression of IPF and other associated comorbidities.

Nintedanib treatment

The treatment of the IPF patients was done using two doses of nintedanib. The basis of choosing 100 mg and 150 mg dose of nintedanib was as per the clinical practice (tolerance and liver functions) followed for the treatment of IPF patients in India. In our clinical practice,

for patients who have low body weight, instead of the usual approach of starting with 150 mg BID and reducing to 100 mg BID if needed, we initiate nintedanib treatment at 100 mg BID, and increase the dose to 150 mg BID at the first follow-up (within 1–2 months), if 100 mg dose is tolerated well. In case 150 mg BID dose is not tolerated, we reduce the dose back to 100 mg BID. Although not supported by recommendations, in our experience, such an approach tends to improve patient compliance to therapy.

The mean duration of exposure to nintedanib ($n = 74$) was 23.3 months. At first visit at our center, nintedanib was prescribed at a starting dose of 100 mg BD to 37 patients, and 150 mg BD to 39 patients. At the time of last observation, the initial dose was unchanged in 57 patients, while 19 patients' dose was modified during treatment (from 100 mg BID to 150 mg BID in 11 patients; 150 mg BID to 100 mg BID in 8 patients).

Changes in forced vital capacity

Out of the 76 patients, 42 patients had FVC data available for at least one follow-up visit after baseline FVC assessment. Total 42 patients, for whom there was a gap of at least 6 months between the first and the

last FVC measurements, were included in the analysis. Mean baseline FVC was 1.7 L; mean duration between first and last measurements was 20.2 months (median 18.1 months).

Mean annualized absolute change in FVC and FVC % predicted from baseline till follow-up was -0.07 L and -1.80% respectively. Age and dose regimen-wise changes in FVC are presented in Table 2. Out of these 42 patients, 20 (47.6%) patients showed either an improvement or a decline of $<5\%$ in FVC % predicted, indicating stable disease. The regression analysis was applied to the data to find the association of the variables with the disease stability. Variables included in the univariate analysis were age, gender, dose, exposure to nintedanib (duration in months), GAP stage, and FVC. The reason for including these variables in the multivariate analysis was based on the biological plausibility, statistical (variables significant from univariate analysis), and clinical significance. On multivariate analysis, it was found that dose regimen usage (150 mg BID), GAP index stage III and high baseline FVC was associated with unstable disease (with adjusted odds ratio 2.83, 2.06, and 1.96 respectively). However, the results were found to be statistically insignificant ($P > 0.05$) [Table 3].

Table 1: Baseline demographic and clinical characteristics of patient population

Characteristics (n , number of patients with available data)	Details
Age (years) ($n=76$), mean (SD)	63.1 (12.5)
	Range (30-86)
<60	25 (32.9)
60-70	27 (35.5)
>70	24 (31.6)
Gender ($n=76$), n (%)	
Male	44 (57.9)
Female	32 (42.1)
Duration of nintedanib treatment (months) ($n=74$), mean (SD)	23.3 (24.0)
TLC (L) ($n=23$), mean (SD)	3.2 (1.0)
	Range (1.5-4.5)
FVC (L) ($n=42$), mean (SD)	1.7 (0.7)
	Range (0.6-3.3)
FVC % predicted (%) ($n=42$), mean (SD)	57.0 (20.0)
DLCO (%) ($n=37$), mean (SD)	37.2 (17.5)
	Range (14-86)
Comorbidities ($n=76$), n (%)	
Type 2 diabetes	38 (50.0)
Hypertension	34 (44.7)
Coronary artery disease	19 (25.0)
Gastro-esophageal reflux disease	17 (22.4)
Hypothyroidism	16 (21.1)
Osteoporosis	15 (19.7)
Obstructive sleep apnea	8 (10.5)
GAP index ($n=69$), n (%)	
Stage I	2 (2.9)
Stage II	32 (46.4)
Stage III	35 (50.7)
6-MWD test (m) ($n=27$), mean (SD)	266.1 (89.6)
	Range (112-532)

TLC: Total lung capacity, FVC: Forced vital capacity, DLCO: Diffusing capacity for carbon monoxide, SD: Standard deviation, 6-MWD: 6 min walk distance GAP: Gender-Age-Physiology Index

Changes in DLCO

We analyzed DLCO data of only those ($n = 37$) patients in whom there was a gap of at least 6 months between the first and last available observations. Mean baseline DLCO was 37.2%; mean and median follow-up duration was 20.0 and 17.1 months, respectively. The mean annualized absolute change in DLCO % predicted was -2.2% . Decline in DLCO % predicted was comparatively lesser in the patients aged ≤ 60 years (-1.3%) and those on 150 mg BD dose at the last observation [Table 4].

Changes in GAP index stage over treatment

GAP index for over at least 6 months was available for 69 patients at baseline and 42 patients at the time of follow-up. At baseline, half of the patients (35, 50.7%) had GAP index stage of III followed by 32 (46.4%) at stage II and 2 (2.9%) at stage I. At the time of follow-up, 1 (2.4%), 17 (40.5%), and 24 (57.1%) patients were at GAP Index Stage I, II, and III, respectively [Figure 1].

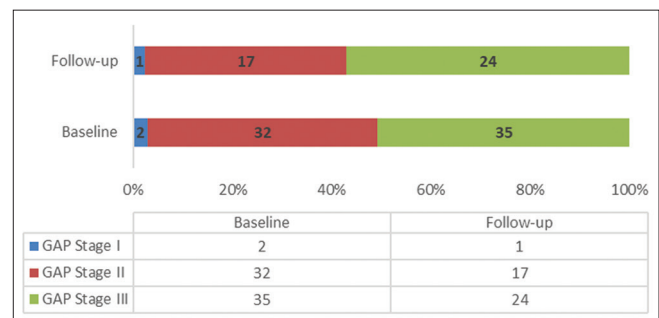


Figure 1: Distribution of patients in GAP index Stage I, II, and III at baseline and follow-up

Table 2: Changes in forced vital capacity over one year in the patient population

Variables	n	Baseline FVC		FVC after 1 year		Change in FVC over 1-year	
		Absolute (L) mean (SD)	Percentage predicted mean (SD)	Absolute (L) mean (SD)	Percentage predicted mean (SD)	Absolute (L) mean (SD)	Percentage predicted mean (SD)
Age (years)							
≤60	20	1.5 (0.6) Range (0.7-3.1)	47.2 (15.7) Range (24.3-74.7)	1.4 (0.5) Range (0.7-2.4)	44.2 (14.1) Range (23.4-68.7)	-0.11 (0.21) Range (-0.7-0.3)	-3.0 (6.5) Range (-17.1-12.6)
>60	22	1.9 (0.7) Range (0.6-3.3)	65.8 (19.7) Range (28.6-110.6)	1.8 (0.7) Range (0.7-3.1)	65.1 (20.0) Range (28.8-109.9)	-0.03 (0.22) Range (-0.4-0.5)	-0.7 (8.2) Range (-15.6-21.4)
Dose regimen (at last observation) (mg BID)							
100	20	1.7 (0.7) Range (0.6-3.1)	53.9 (20.6) Range (28.6-110.6)	1.6 (0.7) Range (0.7-3.1)	53.0 (22.2) Range (23.4-109.9)	-0.06 (0.23) Range (-0.7-0.5)	0.9 (7.3) Range (-17.1-21.4)
150	22	1.7 (0.7) Range (0.7-3.3)	59.7 (19.6) Range (24.3-94.7)	1.6 (0.6) Range (0.7-2.9)	57.1 (18.5) Range (24.9-89.6)	-0.08 (0.21) Range (-0.4-0.4)	-2.63 (7.6) Range (-15.6-13.2)

FVC: Forced vital capacity, SD: Standard deviation

Table 3: Details of the multivariate regression analysis

Parameters	Adjusted odds	CI (2.5%-97.5%)	P
Age	0.99	0.9-1.1	0.738
Gender			
Female	1	1	0.307
Male	0.3	0.03-2.9	
Dose (mg)			
100	1	1	0.158
150	2.83	0.7-12.7	
Exposure (duration in months)	1	0.9-1.0	0.78
GAP stage			
Stage I and II	1	1	0.508
Stage III	2.06	0.3-19.4	
FVC at baseline	1.96	0.5-8.3	0.335

CI: Confidence interval, FVC: Forced vital capacity, GAP: Gender-Age-Physiology Index

6-Minute walk distance(6-MWD)

A total of 42 patients underwent analysis for 6-MWD. Mean baseline 6MWD was 266.1 m and at the time of follow-up, it was 291.4 m. Therefore, the mean absolute change in MWD was 25.3 meters. Patients aged ≤60 years and those who were on 100 mg BID showed a higher decline in 6-MWD as compared to the other categories [Table 5].

Adverse events

Acute exacerbations

Episodes of acute worsening of dyspnea and lung function, without an identifiable cause were termed as acute exacerbations. Seventy-two (94.8%) patients had a history of acute exacerbations prior to starting the nintedanib therapy. Forty-eight (63.2%) patients reported acute exacerbations over the study period [Table 6]. Only mild to moderate exacerbations treated on OPD basis are being taken for evaluation. Since the window of repeat evaluations was 4–8 weeks they were conducted during that period only. These exacerbations required increase oxygen demand and antibiotics with short course of steroids.

Treatment-related adverse events

A total of 6 adverse events (all gastrointestinal) were reported by the patients. The most common adverse event was diarrhea. One patient discontinued the drug

permanently; others could be managed by reducing the dose of nintedanib, and symptomatic management, including the use of loperamide [Table 6].

DISCUSSION

The study provides insights related to the IPF patients met in clinical practice in India. While clinical trials provide a higher level of evidence, the participants are more selected and may not include all types of patients in whom the drug will be finally used in clinical practice. Real-world evidence thus fills up this gap and provides data on a drug's safety and efficacy in a wider set of patients.^[8] The findings of the present study revealed that nintedanib bear potential in reducing the %FVC and DLCO and improving 6-MWD in IPF patients. Further, only 6 patients reported adverse events which were also mild and were managed by dose reduction. This reflected the tolerability of nintedanib in IPF patients. Thus, nintedanib can be used for alleviating the symptoms experienced in IPF.

Our study involves a relatively large set of IPF patients and provides important information on the characteristics of Indian IPF patients seen in clinical practice. There are differences when we compare our study's population with that of INPULSIS trials'. Our patients were relatively young (mean age 63 years vs. 67 years). FVC % predicted was substantially lower than that in INPULSIS trials (57.0% in our study). This finding was not unexpected. The awareness on IPF/ILD is low in India, both among general public and physicians.^[9] It is not unusual for the patient to be first treated for an alternative diagnosis before a diagnosis of IPF is made. It was observed, for example, in a study from western India, that the median delay in diagnosis of IPF was 20 months, and >20% of patients had wrongly received anti-tuberculosis drugs before they were diagnosed with IPF.^[10] These observations indicate the need to increase awareness of IPF and other ILDs. General practitioners are usually the first point of medical contact and should be trained adequately to differentiate between ILDs from other respiratory disorders, to allow prompt referral of such patients to expert centers.

Table 4: Changes in diffusing capacity for carbon monoxide over one year according to age and last dosage regimen

Variables	n	Mean (SD)		
		Baseline DLCO absolute percentage predicted	DLCO after 1 year Absolute percentage predicted	Change in DLCO over 1 year percentage predicted
Age (years)				
≤60	15	29.8 (14.3) Range (14-59)	28.5 (16.4) Range (6.7-62.3)	-1.3 (13.7) Range (-24.2-35.3)
>60	22	42.3 (18.0) Range (15-86)	39.4 (17.4) Range (15-73.9)	-2.9 (11.6) Range (-22.7-31.3)
Dose regimen (at last observation) (mg BID)				
100	17	34.1 (13.6) Range (15-58)	30.7 (15.4) Range (6.7-62.3)	-3.4 (13.3) Range (-24.3-35.3)
150	20	39.9 (20.2) Range (14-86)	38.7 (18.9) Range (12.9-73.9)	-1.2 (11.7) Range (-22.7-31.3)

DLCO: Diffusing capacity for carbon monoxide, SD: Standard deviation

Table 5: Changes in 6 min walk distance over one year according to age and last dosage regimen

Variables	n	Mean (SD)		
		Baseline 6-MWD absolute (m)	6-MWD after 1 year absolute (m)	Change in 6-MWD over 1 year absolute (m)
Age (years)				
≤60	20	272.3 (103.4) Range (112-532)	322.8 (108.6) Range (196-518)	50.4 (101.0) Range (-112-82)
>60	22	261.1 (80.3) Range (150-392)	266.3 (116.0) Range (108-512)	5.2 (94.8) Range (-140-156)
Dose regimen (at last observation) (mg BID)				
100	20	242.8 (103.0) Range (112-532)	281.7 (112.8) Range (108-512)	38.9 (90.7) Range (-126-182)
150	22	295.2 (61.6) Range (180-392)	303.5 (119.8) Range (140-518)	8.3 (108.8) Range (-140-182)

6-MWD: 6 min walk distance, SD: Standard deviation

Table 6: Details of adverse events

Acute exacerbations	n (%)
Total number of patients	76
Number of patients having a history of acute exacerbations	72 (94.8)
Number of patients reporting acute exacerbations over the study period	48 (63.2)
Adverse events	
Total number of patients	76
Number of patients came for follow-up	48
Number of patients reported adverse events	6 (12.5)
Loose stools/diarrhoea	2
Constipation	1
Abdominal cramps	1
Abdominal fullness	1
Loss of appetite	1

In the INPULSIS trials, majority of the patients were in GAP stage I, followed by stage II and III (47.2%, 46.1%, and 14.5% in GAP stages I, II, and III, respectively). This is in contrast with our data wherein we found that majority of patients were in GAP stage III, followed by stage II, and a very few patients in stage I (2.9%, 46.4%, and 50.7% in GAP stages I, II, and III, respectively). This too can be attributed to late presentation of Indian IPF patients, owing to delays in diagnosis. It would not be surprising then if the average survival of Indian IPF patients was found to be lower than their western counterparts. It may be somewhat heartening, however, to note that nintedanib provides a similar beneficial effect on FVC decline in patients at GAP

stage I vs. stage II/III, according to a *post hoc* analysis of INPULSIS trials.^[11]

When compared with a few other real-world studies with nintedanib in IPF across the world [Table 7], the patients in our study, in general, had lower age, lower FVC % predicted, and similar rates of comorbid conditions (except for diabetes, which was higher in Indian patients). DLCO% was found to nearly same with respect to other studies. The proportion of males in our study was lower than that in INPULSIS trials, and in other real-world studies, although in our study too males outnumbered females. It is important to note, however, that despite small differences in the patient characteristics, our findings were generally similar to other real-world studies– nintedanib seems to stabilize the lung function in IPF in majority of patients and is well tolerated. This supports that fact that nintedanib is efficacious in a wide variety of IPF patients.

Recently, a study on tolerability of another antifibrotic agent, i.e., pirfenidone has been conducted for assessing its effect on the survival in IPF. The results revealed that pirfenidone was well-tolerated among the patients but showed increase in survival only with the full dose. The annualized fall in % predicted FVC was found to be similar across both the doses. The most common adverse events reported with this drug were anorexia, dyspepsia,

Table 7: Comparison of real-world Indian studies with western counterparts

Variables	Real world studies								India Mullerpattan <i>et al.</i> ^[7]
	America USA Galli <i>et al.</i> ^[12]	Europe UK Toellner <i>et al.</i> ^[13]	Germany Bonella <i>et al.</i> ^[14]	Germany Brunnemer <i>et al.</i> ^[15]	Greece Tzouveleki <i>et al.</i> ^[16]	Japan Nakamura <i>et al.</i> ^[17]	Japan Kataoka <i>et al.</i> ^[18]	Current study	
Number of patients	57	187	62	64	94	22	37	76*	20
Clinical characteristics									
Male, <i>n</i> (%)	34 (59.6)	142 (76)	48 (77)	55 (85.9)	72 (76.6)	20 (91)	31 (84)	44 (57.9)	15 (75)
Age (years) mean (SD)	71 (8)	72 (8)	71 (8)	70.3 (6.8)	73.8 (7.8)	Median 71.5	70.4 (6.5)	63.1 (12.5)	60.00
Comorbidities, <i>n</i> (%)									
Coronary artery disease	14 (24.6)	43 (23)	8 (13)	21 (32.8)	20 (21.3)	-	-	19 (25.0)	-
Diabetes mellitus	15 (26.3)	37 (20)	9 (14.5)	16 (25.0)	18 (19.1)	-	-	38 (50.0)	-
Gastroesophageal reflux disease	31 (54.4)	19 (10)	7 (11)	21 (32.8)	38 (40.4)	-	-	17 (22.4)	-
Obstructive sleep apnoea syndrome	-	-	4 (6)	9 (14.1)	-	-	-	8 (10.5)	-
Baseline lung function (efficacy parameters)									
DLCO %, mean (SD)	35 (13)	43.9 (15)	40 (10)	37 (10)	44.4 (14.5)	Median 64.0	-	37.2 (17.5)	-
FVC% predicted, mean (SD)	66 (17)	81.1 (19.8)	64 (17)	71 (21)	68.1 (18.3)	Median 63.0	-	57.0 (20.0)	1.43 L (mean predicted: 50.4%)
Adverse events (safety parameters), <i>n</i> (%)									
Diarrhoea	30 (52.6)	185 (98.9)	39 (62.9)	21 (32.8)	52 (55.3)	16 (73)	-	4 (50)	-
Nausea/vomiting	20 (33.3)	123 (65.8)	16 (25.8)	2 (3.1)	29 (30.8)	2 (9)	-	-	-
Dyspepsia/abdominal pain, bloating and wind	3 (5.3)	58 (31.0)	4 (6.5)	-	9 (9.5)	-	-	1 (12.5)	-
Reduced appetite/anorexia	3 (5.3)	65 (34.8)	24 (38.7)	-	18 (19.1)	-	-	1 (12.5)	-
Constipation	-	-	-	-	-	-	-	1 (12.5)	-
Abdominal fullness	-	-	-	-	-	-	-	1 (12.5)	-
Dose reduction, <i>n</i> (%)	12 (21.1)	22 (12)	21 (34)	8 (13)	-	-	-	8 (10.5)	4 (20)
Drug discontinuation, <i>n</i> (%)	15 (26.3)	39 (21)	25 (40)	-	20 (21.2)	12 (55)	-	-	4 (20)
Acute exacerbation on therapy, <i>n</i> (%)	6 (10.5)	-	-	11 (17)	-	-	-	48 (63.2)	-

*Our real-world study. DLCO: Diffusing capacity for carbon monoxide, FVC: Forced vital capacity, SD: Standard deviation

and nausea, which were in accordance with the previous real-world studies.^[19] Conversely, another research reported that Pirfenidone did not show any significant beneficial effect in IPF patients.^[20]

Our study adds to a previous, relatively small, but important Indian study that provided initial data on the Indian experience of nintedanib use in 20 patients with IPF. The mean age (60 years) and FVC % predicted (50.4%) in that study are similar to what we observed in our patients. Importantly, although diarrhea was the most common adverse effect in both the studies, it was manageable with dose reductions. Only one patient in our study permanently discontinued the drug because of diarrhea.

Study strengths and limitations

This is the largest real-world study from India, assessing the characteristics of IPF patients, and effectiveness and safety of nintedanib in IPF patients. However, as with most other real-world studies, the limitations include retrospective data collection and heterogeneity of patients. In addition, compliance to therapy and quality of life was not assessed. Furthermore, as it is single-center study conducted in northern India, the results could not be generalized to the whole population.

CONCLUSION

The study provides the largest data from India, of real-world use of nintedanib in IPF. The results indicate that Indian patients are, on an average, younger than their western or Japanese counterparts. Indian patients tend to have worse FVC % predicted at the time of diagnosis. This might be attributable to delay in seeking treatment and/or in making an appropriate diagnosis, which calls for an increase in the awareness of ILDs in general public and physicians. Our results support the findings from clinical trials and other real-world studies, that nintedanib is effective in slowing down IPF progression, and is generally well tolerated.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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